IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION MDL No. 2187

THIS DOCUMENT RELATES TO C. R. BARD WAVE 4 & WAVE 5 CASES BEFORE JUDGE GOODWIN:

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Robert D. Tucker, Ph.D., M.D.)

The plaintiffs filed their Notice of Adoption of Prior Daubert Motion of Robert D. Tucker, PH.D. for Waves 4 and 5 Cases ("Notice") [ECF No. 4550] in *In re C. R. Bard, Inc.*, *2:10-md-2187*, MDL 2187, on September 27, 2017. The plaintiffs attached as exhibits to their Notice a motion [ECF No. 4550-1], memorandum in support [ECF Nos. 4550-2, 4550-3 & 4550-4], and reply brief [ECF 4543-5], which plaintiffs seek to adopt and incorporate as their briefing for Waves 4 and 5. Defendant also adopted and incorporated by Notice of Adoption of C.R. Bard, Inc.'s Prior Opposition to Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Robert D. Tucker, PH.D., M.D., and Brief in Support for Wave 4 and Wave 5 Cases, a brief in response to plaintiffs' Motion. [ECF No. 4648]. The court construes the plaintiffs' Notice as a motion. As such, the Notice is now ripe for consideration because the briefing is complete. As set forth below, the plaintiffs' motion is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 16,000 cases currently pending, approximately 1,500 of which are in the Bard MDL, 2187 MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). In an effort to manage the massive Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, a docket control order subjects each case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order ("PTO") # 236 (establishing Wave 4); PTO # 244 (establishing Wave 5). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure for cases designated in Wave 4 and Wave 5. The court instructed the parties to file briefing on general causation issues

in the main MDL, MDL 2187, while specific causation *Daubert* motions, responses, and replies were to be filed in the individual member cases. To the extent that an expert is both a general and specific causation expert, the court advised the parties that they could file a general causation motion in the main MDL and a specific causation motion in an individual member case. *See* PTO # 236, at 4; PTO # 244, at 4.

Before plunging into the heart of the motion, and to clarify the record, I am compelled to comment on the manner in which the parties filed the instant *Daubert* motion and response in opposition. Similar to other *Dauberts* filed in the main MDL, the plaintiffs filed the instant motion as a "Notice," adopting and incorporating the entirety of a motion and its corresponding papers filed in a previous case before the court. Defendant C. R. Bard, Inc. ("Bard"), likewise, filed its opposing briefs in conjunction with a similar "Notice." The parties then attached the substance of their briefs, i.e., the supporting or opposing memorandum of law, as an exhibit to their respective Notice. So, for example, the plaintiffs attach the memorandum in support of their *Daubert* motion as "Exhibit 1" to their Notice. The plaintiffs also integrate into Exhibit 1 vital supporting papers, such as the expert report and deposition transcripts demarcated rather confusingly within Exhibit 1 as "Exhibit 1" and "Exhibit 2" respectfully, forming one large document. With this in mind, the court turns its attention to the present dispute.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods" which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct" – "[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (quoting *Daubert*, 509 U.S. at 596 (alteration in original)); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands

is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (citation omitted)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The

> consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted). At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

III. Discussion

Bard offers Dr. Robert D. Tucker, a pathologist and professor of bioengineering, to address pathology issues related to the Avaulta and the Align products sold by Bard for POP and SUI repair that are the subject of this pending litigation. *See* Notice of Adoption of Prior Daubert Mot. of Robert D. Tucker, Ph.D, for Waves 4 & 5 Cases, Ex. 1 ("Dr. Tucker's Expert Report"), at 3 [ECF No. 4550-1]. The plaintiffs object to certain opinions advanced by Dr. Tucker; specifically, testimony regarding FDA approval, the credibility of plaintiffs' experts, the Material Safety Data Sheet ("MSDS") of the polypropylene used by Bard in the manufacture of the mesh products, and position statements published by medical group on midurethral slings.

A. Opinions Regarding FDA Approval

Many of the *Daubert* motions filed in this MDL raise the same or similar objections. This particular issue has been a staple in this litigation. I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs – a position that has been affirmed by the Fourth Circuit – and will continue to do so in this case. *See In re C. R. Bard, Inc.*, 81 F.3d 913, 921-23 (4th Cir. 2016)

(upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See id.* at 920 ("[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value."). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors "to erroneously conclude that regulatory compliance proved safety." *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process is **EXCLUDED**. For the same reasons, opinions about Bard's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Therefore, the plaintiffs' motion on this point is **GRANTED**.

B. Opinions on the Credibility of Plaintiffs' Experts

The plaintiffs also seek to exclude certain statements made by Dr. Tucker that challenge the credibility of Dr. Klosterhalfen, an expert certain plaintiffs intend to proffer. In short, the plaintiffs believe certain statements by Dr. Tucker are beyond a permissible critique of an opposing expert witness. Bard concedes the issue in response, stating that Dr. Tucker will not provide opinions regarding the credibility of Dr. Klosterhalfen. As such, insofar as Dr. Tucker's testimony usurps the province of a jury to determine a witness's credibility, the plaintiffs' Motion is **GRANTED** and

such statements are **EXCLUDED**. However, statements by one expert assessing or analyzing another expert's substantive testimony or the reliability of their opinions are permissible.

C. Opinions Regarding MSDS

Next, the plaintiffs seek to prevent Dr. Tucker from testifying on the utility and interpretation of language contained in MSDSs. As I have previously held, the pertinent issue is not whether doctors rely on or heed MSDS warnings for the raw materials Bard uses to manufacture its medical devices. *See Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 507, 577 (S.D. W. Va 2014 (excluding a doctor's opinions on the MSDS because "[a] narrative review of the history and development of MSDSs and who uses them in the field is not helpful to the jury"). Nevertheless, I acknowledge the need for rebuttal testimony based on what the plaintiffs present at trial. Accordingly, I **RESERVE** ruling on the admissibility of Dr. Tucker's MSDS opinions for trial.

D. Position Statements

Last, without identifying a particular opinion proffered, the plaintiffs seek to prevent Dr. Tucker from testifying on any issues wherein his opinion on the matter derives from position statements published by certain medical groups, including the AUGS/SUFU Position Statement regarding transvaginal mesh and midurethral slings. *See* Notice of Adoption of Prior Daubert Mot. of Robert D. Tucker, Ph.D, for Waves 4 & 5 Cases, Ex. 1 ("Pls.' Mem. in Supp."), at 12–15 [ECF No. 4550-1].

As an initial matter, I agree that Bard cannot use Dr. Tucker as a mouthpiece for the AUGS/SUFU Position Statement—simply reading a document into evidence does not require "scientific, technical, or other specialized knowledge." Fed. R. Evid.

702. Nor can Dr. Tucker represent to the jury that the AUGS/SUFU Position Statement embodies a legal conclusion or a standard of care. *See United States v. McIver*, 470 F.3d 550, 572 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard . . . is generally inadmissible."). To the extent Dr. Tucker seeks to use the Position Statement in this manner, plaintiffs' Motion is **GRANTED** and his opinions are **EXCLUDED**.

The plaintiffs also argue that a Position Statement is not a reliable basis for an expert opinion because such statements are unscientific and litigation-driven. *See* Pl.s' Mem. in Supp., at 13. Even if this is true, the unreliability of one source used by an expert in reaching his opinion does not call for the exclusion of that opinion altogether, assuming the expert considered other reliable sources in his methodology. Therefore, to the extent the plaintiffs seek to exclude any of Dr. Tucker's opinions merely because he relied, in part, on the Position Statement, their motion is **DENIED**.[1]

IV. Conclusion

For the reasons stated above, the court **ORDERS** that the plaintiffs' Notice of Adoption of Prior Daubert Motion of Robert D. Tucker, PH.D. for Waves 4 and 5 Cases [ECF No. 4550], which the court construed as a motion, is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**.

[1] The plaintiffs also seem to argue that Dr. Tucker should not be permitted to reference the Position Statement at all. This argument goes to the admissibility of the Position Statement, rather than the admissibility of Dr. Tucker opinions, and is therefore better suited for a motion *in limine*. Accordingly, I do not address it at this time.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:10-md-2187, and the Bard Wave 4 and Wave 5 cases identified in the Exhibit attached hereto. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: September 5, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit A

CIVIL ACTION NUMBER	Case Name
2:14-cv-03439	Kitchen v. C. R. Bard, Inc. et al.
2:14-cv-18890	McManus v. C. R. Bard, Inc. et al.
2:14-cv-21874	McCray v. C. R. Bard, Inc. et al.
2:14-cv-23401	Barber v. C. R. Bard, Inc. et al.
2:14-cv-28943	Smith et al. v. C. R. Bard, Inc. et al.
2:16-cv-01855	Eiffler v. Sofradim Production SAS et al.